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(54) Title: STABLE LAMOTRIGINE PHARMACEUTICAL COMPOSITIONS AND PROCESSES FOR THEIR PREPARATION

(57) Abstract: The present invention relates to a stable pharmaceutical composition of lamotrigine and pharmaceutically acceptable acid addition salts thereof. The invention also relates to a process for the preparation of such a composition. The pharmaceutical composition includes: (a) from about 0.1% to about 50 % by weight of lamotrigine or acid addition salt thereof; (b) from about 15.5% to about 70% by weight of microcrystalline cellulose; (c) from about 0.1% to about 14.5% by weight of sodium starch glycolate; and (d) from about 0.1% to about 4.5% by weight of polyvinylpyrrolidone

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/20 A61K31/53

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|-----------------------|
| X | WO 92/13527 A (WELLCOME FOUND) 20 August 1992 (1992-08-20) page 3, last paragraph - page 4, paragraph 1 page 21, paragraph 7 - page 26 examples 32-40 claims 1-14, 19-30 | 1-29 |
| X | GLAXO WELLCOME INC.: "Lamictal tablets - FDA approved labeling text" INTERNET CITATION, 'Online! 2001, XP002296818 Retrieved from the Internet: URL: http://www.fda.gov/cder/foi/label/2001/20764s51b1.pdf 'retrieved on 2004-09-15! page 2 | 1-29 |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2004/000820

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 28 and 29 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

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